

## Clinical Edit Criteria Proposal

Drug/Drug Class: Amitiza® Capsules Clinical Edit

Date: December 13, 2006

Prepared for:

Prepared by: Missouri Medicaid

☒ New Criteria

☐ Revision of Existing Criteria

### Executive Summary

**Purpose:** Ensure appropriate utilization and control of Amitiza® (lubiprostone capsules).

**Why was this Issue Selected:**

Amitiza® is a branded drug product containing lubiprostone indicated for the treatment of chronic idiopathic constipation in adults. This medication locally targets intestinal chloride channels to help regulate fluid balance. Chronic idiopathic constipation is generally defined as infrequent and difficult passage of stool and is one of the most common disorders suffered by Americans. This condition affects women more often than men and also affects those over the age of 65 more frequently. Symptoms include abdominal pain and discomfort, bloating, straining, and hard stools. Amitiza® is available in a 24 mcg capsule, dosed BID, and is priced higher than other agents used to treat this condition.

Program-specific information:	Drug	Cost per Claim
	• Senokot-S	\$11.85WAC
	• Polyethylene Glycol Pwdr	\$26.03WAC
	• Zelnorm®	\$155.40WAC
	• Amitiza®	\$160.20WAC

**Setting & Population:** Adult patients.

**Type of Criteria:** ☐ Increased risk of ADE

☐ Non-Preferred Agent

☒ Appropriate Indications

☐

Data Sources: ☐ Only administrative  
databases

☒ Databases + Prescriber-  
supplied

## Setting & Population

- Drug for review: Amitiza® (lubiprostone capsules)
- Age range: Adult patients
- Gender: Male and female

## Approval Criteria

- Appropriate diagnosis – Constipation
- Trial and failure on at least 2 different covered laxative preparations
- ADE/ADR to covered laxative products
- Contraindication to covered laxative products

## Denial Criteria

- No prior prescription claims for covered laxative product in the most recent 45 days
- Lack of ADE/ADR and/or lack of contraindication to covered laxative products
- Lack of appropriate diagnoses

## References

1. Facts and Comparisons, p.1164a – 1164b. 2006.
2. USPDI, Micromedex, 2006.
3. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2006.
4. Takeda Pharmaceuticals America Inc., “Amitiza, Lubiprostone Capsules Product Submission”, Lincolnshire, IL 60069; March 2006.

